

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Neo Baby Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetrimide BP 0.2%

Benzalkonium Chloride 50% BP 0.1%

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment and prevention of rashes caused by chafing such as napkin rash.

4.2 Posology and method of administration

At each nappy change apply to the baby's bottom after first washing and drying the skin.

4.3 Contraindications

Do not use the cream if the infant is known to be sensitive to any of the ingredients.

4.4 Special warnings and precautions for use

The cream contains a derivative of lanolin which may cause local skin reactions eg. contact dermatitis.

Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a

serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions recorded when used as directed.

4.6 Pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

None recorded

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the yellow card scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The active agents are both Quaternary Ammonium compounds which are bactericidal agents. They help reduce bacterial breakdown of urea in the urine which is a major cause of napkin rash.

5.2 Pharmacokinetic properties

The active agents are held in solution and available for topical effect. The cream base also contains Silicone Oil which while not declared as an active does help form a surface barrier on the skin.

5.3 Preclinical safety data

None recorded.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetyl Alcohol,

Non Ionic Emulsifying Wax,

White Soft Paraffin,

Propyl Hydroxybenzoate,

Silicone Oil,

Poloxyethylene Lanolin Complex,

Perfume and Purified Water.

6.2 Incompatibilities

Quaternary Ammonium Compounds have their activity reduced by any residual soap left on the baby's skin.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25°C.

Do not freeze.

6.5 Nature and contents of container

50g Aluminium Tube,

125g Polypropylene Tub.

6.6 Special precautions for disposal

No special instructions required.

7 MARKETING AUTHORISATION HOLDER

Neo Laboratories Ltd.

51-53 Stert Street

Abingdon

Oxfordshire OX14 3JF

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 02019/5002R

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3 June 1987 / 23 September 1992

10 DATE OF REVISION OF THE TEXT

03/06/2019